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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,722	03/28/2002	Ralf-Peter Franke	CERA-233	7010
24972	7590	07/14/2004	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			DAVIS, DANIEL J	
			ART UNIT	PAPER NUMBER
			3731	
DATE MAILED: 07/14/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/937,722

Applicant(s)

FRANKE ET. AL.

Examiner

D. Jacob Davis

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 42-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 55 and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to disclose the particular phase or phases "of the kind contained in ceramics for cutting metal."

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "of the kind" renders the claims indefinite because the claims include elements not actually disclosed (those encompassed by "of the kind"), thereby rendering the scope of the claims unascertainable. See MPEP § 2173.05(d).

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 42, 44, 45, 47-51, 53 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,559,824 to Soma et al. Soma discloses a zirconium oxide and aluminum oxide (see charts) used as a surgical knife and scissors (Col. 7, lines 32-35). The scissors and knife are both considered a thread cutting tool. Since the materials are the same as those claimed by applicants, they inherently are biocompatible and bioinert. Since there is no iron, no iron particles will form.

Claims 42-45, 47-49, 51, 53 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,641,251 to Leins et al. Leins discloses a drill bit in Fig. 1 comprised entirely of an aluminum oxide ceramic (Col. 2, lines 26-28). The ceramic is a bioinert biocompatible, high strength ceramic. Although they do not disclose the drill bit as a "surgical instrument," it may be used as such.

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Claims 42, 44, 45, 47-51, 53 and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,871,547 to Abouaf et al. Abouaf disclose a hip joint prosthetic having a head comprising YTZP (Col. 4, lines 29--et seq.). The prosthetic is considered a surgical instrument or tool because it is used to connect the hip. The device is made of a bioinert biocompatible, high strength ceramic. Col. 4, lines 56-57 describe the surface "consisting essentially of 100% tetragonal zirconia," or YTZP.

Claims 42- 45, 47-51, 53 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Hood. Hood discloses an ultrasonic surgical knife (Col. 1, lines 14-28) having teeth comprising a metal base with an aluminum oxide ceramic coating (Col. 7, lines 30-55). Since the device has teeth, it is also considered a saw. Since they are silent regarding any impurities contained in the ceramic coat, the coat "*consists of the biocompatible bioinert material.*" Since the outer coating comprises no ferrous materials, the instrument will not "form iron particles during use."

Claim 58 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,797,939 to Yoon. Yoon discloses a surgical tool in Fig. 1. The tool has titanium blades 18 and 20 (col. 5, lines 4-9) that may be sterilized for a successive use (col. 6, lines 34-38 and col. 9, lines 5-8). Inherently, the titanium blades do not form iron particles during use.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(c) which forms the basis for all obviousness rejections set forth in this Office action:

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,559,824 to Soma et al. in view of DE 43 13 305. Soma discloses biocompatible scissors, but fails to disclose that each blade has a different hardness. Nevertheless, the '305 patent teaches that it is beneficial to make the blades having a different hardness in order to increase the operational life of the blades. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the Soma blades such that one blade was harder than the other to increase the operational life of the device.

***Response to Arguments***

Applicant's arguments filed February 17, 2004 have been fully considered but they are not persuasive. Since the materials described as the effecting portions of each of the Soma, Leins, Abouaf, and Hood do not have ferrous materials, they inherently would not form ferrous particles during use. Moreover, at least some of the materials described in each patent are the same as recited in the claims. Therefore, the materials must be biocompatible as stated by applicants.

With respect to the Leins et al. reference, it is noted that Leins et al. anticipates certain claims. Under the law of anticipation, it is only necessary that the claim in question "read on" the reference. As to the functional recitations, it is only necessary that the prior art be "capable of" performing the recited intended functions. The all-ceramic drill but of Leins et al. is fully capable of performing as a medical or surgical instrument, e.g. drilling a bone. Similarly, the Abouaf et al. reference is fully capable of performing as a medical or surgical instrument, e.g. hammering a nail into bone.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

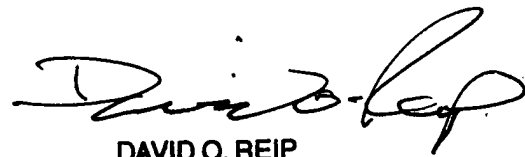
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJD  
June 30, 2004

A handwritten signature in black ink, appearing to read "David O. Reip", is written over the printed name and title.

DAVID O. REIP  
PRIMARY EXAMINER